EXPRESS MAIL NO. EV 333 999 132 US LIFE-037 Attorney Docket **Information Disclosure** First Named Inventor Pugh, Jerry T. **STATEMENT** 5894 Confirmation Number 7 2003 10/029,525 **Application Number** Address to: Mail Stop RCE Filing Date December 21, 2001 Commissioner for Patents 3653 P.O. Box 1450 Group Art Unit Alexandria, VA 22313-1450 NOLAND, KENNETH W. **Examiner Name** "TEST DEVICE WITH MEANS FOR STORING AND Title: DISPENSING DIAGNOSTIC

Sir:

SEP

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This is an Information Disclosure Statement submitted for the Property A Form SB08 (substitute for form 1449) listing the reference accompanies this paper. Applicants would appreciate the Examiner initialing and returning the form to indicate that the reference has been reviewed and made of record.

More specifically, the Applicant is submitting photographs and a description of a glucose monitoring system (the "System") that Applicant has been made aware of. The System (brand name "INTEGRA") was manufactured by Apprise, Inc., a company that is no longer in business. Reasonable efforts have been made by Applicant to find information about the INTEGRA system. However, Applicant has been unable to locate any documentation, including any product literature, relating to the INTEGRA system. However, a search of the U.S. Food & Drug Administration's ("FDA") website, and more specifically the FDA's 510(k) Premarket Notification Database accessed online via the world wide web, has uncovered a premarket notification (510(k)) summary relating to the INTEGRA Blood Glucose Monitoring System, a copy of which is herewith included. The premarket notification (510(k)) summary shows a "Date Received" of May 2, 1989 and a "Decision Date" of August 3, 1989. Furthermore, Applicant has been unable to verify specific dates relating to public knowledge of the System. However, Applicant believes that the INTEGRA system was in development at least as early as 1989, as evidenced by the 510(k) summary sheet, and was shown at a tradeshow in the early 1990's.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C. §102.

Applicant(s) hereby petition for the consideration of this Information Disclosure Statement.

LFS-124

Atty Dkt. No.: LIFE-037 USSN: 10/029,525

As applicants have not yet received a first Action on the merits, no fee is believed to be required for filing this Disclosure Statement. If, however, the PTO finds that for some reason a fee is due, our Deposit Account No. 50-0815, Order No. LIFE-037 may be charged thereon.

Respectfully submitted, BOZICEVIC, FIELD & FRANCIS LLP

Date: $\frac{9/1/03}{}$

By:

Reg. No. 52,272

BOZICEVIC, FIELD & FRANCIS LLP 200 Middlefield Road, Suite 200

Menlo Park, CA 94025 Telephone: (650) 327-3400

Facsimile: (650)327-3231 F:\DOCUMENT\life\037\ids pugh.doc

PTO/SB/08a (05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO				Complete if Known		
				Application Number	10/029,525	
INFORMATION DISCLOSURE				Filing Date	December 21, 2001	
STATEMENT BY APPLICANT (use as many sheets as necessary)				First Named Inventor	Pugh, Jerry T.	
				Art Unit	3653	
				Examiner Name	NOLAND, KENNETH W.	
Sheet	1	of	1	Attorney Docket Number	LIFE-037	

			U.S. PATENT	DOCUMENTS	
Examiner Initials'	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant <u>Figures Appear</u>
		US-			

		FOREIG	N PATENT DOC	UMENTS			
Examiner Initials'	Cite No.¹	Foreign Patent Document	1	Name of Patentee or Applicant of Cited Document		Pages, Columns, Lines	
		Country Code ³ –Number ⁴ –Kind Code ⁵ (if known)				or Relevant Figuree-Appear	
		Country code (Name)				SEP 3 0 2003	-
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Examiner					Date		

Considered

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²		
	C1	Website//www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMN.CFM?id=58028 (9/15/2003)			
	C2	Description of INTEGRA Blood Glucose Monitoring System			

Examiner	Date
Signature	Considered
Signature	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signature